

Research



Effective methods for diagnosis, treatment, and prevention of cancer rely on evidence generated from closely interrelated basic and clinical research. Basic research adds to the understanding of the biology of cancer and is invaluable in designing applications to human disease. Observations of disease development drive basic research studies. Translational research, an intermediate step, links bench science and bedside clinical medicine. Overall, carefully collected and interpreted evidence has the ability to improve outcomes for patients with cancer.

Clinical trials are research studies involving people. They represent the final stages of this long and careful cancer research process. When an approach demonstrates promise, clinical trials or investigations are designed on a scientific data-driven basis to find out if it is safe, effective, and better than the current standard of care. This allows research to advance without compromising current standards of care.

Clinical trials are performed in accredited cancer treatment centers with formal mechanisms that protect the patient, the facility, and the healthcare provider. Patients participating in clinical trials have access to potentially more effective and less costly approaches. The outcomes for the same type and stage of cancer are often better for those participating in clinical trials. They also offer patients and researchers opportunities to contribute to the body of knowledge. Trials have the potential to improve personal care and make lasting contributions to the field of medicine.

Participation in clinical trials is voluntary. Nationally, only two to three percent of cancer patients are treated in clinical trials. Identifying and overcoming barriers to participation can provide better care and data for emerging advances in cancer management and prevention. Financial and other barriers to participation exist for patients and providers. Health insurance providers may not cover the routine patient care costs for patients in clinical trials.

The best management for any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

— National Comprehensive Cancer Network (NCCN)

Clinical trials: Research studies involving people that test new, promising prevention and treatment methods to determine whether they are safe, effective, and better than current standards of care.

This Comprehensive Cancer Control Plan proposes a centralized person as a resource for scientifically sound cancer information. The liaison will provide an effective, coordinated mechanism to increase awareness of cancer-related issues in Montana. The cancer medical liaison will perform multiple tasks.

- Develop and implement tools, including a web-based resource, that provide up-to-date information for patients, healthcare providers, insurance providers, policymakers, and basic researchers. The tools will facilitate participation in basic cancer research, appropriate utilization of translational technology, and increased utilization of clinical trials in Montana.

- Respond to healthcare professionals by providing access to evidence-based information that improves the effective, efficient use of new technologies as they progress to state-of-the-art and become standards of care.
- Organize educational opportunities through a speakers' bureau, seminars, teleconferences, web links, funding opportunities, and translational technology directed toward cancer management.

Basic, translational, and clinical research all offer advances to cancer management. Overcoming barriers to participation in cancer research for both patients and professionals needs to be addressed through educational efforts that are accurate, easy to access, comprehensive, up-to-date, and responsive to need. Through awareness and education, there is an opportunity to reach all populations in Montana that may benefit from cancer research activity in all of its forms.

"The genius, then, is in the bridge or the translation." — Dr. Grant Harrer

Goal I: Provide professionals and the public access to cancer research information.

Objective I.1: *Create a list of web links relating to science- and evidence-based cancer information.*

Baseline: There is no identified comprehensive list of web resources available

Outcomes: By 2008, a list will be available online and routinely maintained

Data sources: Process evaluation results

Strategy 1	Identify and review possible websites and generate a list of links to science- and evidence-based cancer information.
Strategy 2	Maintain the resource list on the Cancer Control webpage, and market this resource to the public and providers.

“The process of scientific discovery is, in effect, a continual flight from wonder.” – Albert Einstein

Objective I.2: *Create a position for a liaison to serve as a cancer information resource for healthcare providers and the public.*

Baseline: There is no central liaison resource available

Outcomes: By 2011, establish a liaison and make her/him available statewide through a toll-free help line

Data sources: Process evaluation results

Strategy 1	Create a job description and identify a physical location and funding for the central liaison. Position duties will include such tasks as: coordination of professional education programs; information management; resource dissemination; and organization of a speakers' bureau, teleconferences, and other activities.
Strategy 2	Establish a toll-free help line for access to the liaison and market this resource to providers and the public.

Objective I.3: *Establish an educational program on state-of-the-art, cancer-related practices.*

Baseline: No comprehensive educational program is available

Outcomes: By 2011, create and institute a professional educational program on state-of-the-art, cancer-related practices

Data sources: Process evaluation results

Strategy 1	Establish this program and coordinate it through the central liaison described in Objective 1.2.
Strategy 2	Market this resource to providers and the public. Include information on the program in professional cancer education statewide.

Goal II: Assure high-quality cancer research in Montana.

Objective II.1: *Increase the percentage of Montana cancer patients who participate in clinical trials.*

Baseline: 2.2 percent of all eligible patients were in clinical National Cancer Institute (NCI) trials in Montana

A percent of patients in other clinical trials will be determined from private companies and other in-house clinical trials

Outcomes: By 2008, determine the percentage of Montana cancer patients who are participating in clinical trials

By 2011, increase the baseline level of participation by a percentage to be determined

Data sources: Montana Cancer Consortium (MCCC) 2003 for NCI trials; pharmaceutical, private, and in-house clinical trials — method to be established

Strategy 1	Implement a tool to determine the percentage of Montana cancer patients who are participating in clinical trials.
Strategy 2	Educate healthcare providers and the public on clinical trials available to Montanans of all ages. Provide on-going public education on the benefits and limitations of clinical trials.
Strategy 3	Encourage care coordinators to inform cancer patients of clinical trials germane to their conditions; increase the number of healthcare providers recommending clinical trials to their patients.
Strategy 4	Support policies encouraging public and private insurers to make appropriate reimbursements for routine patient care costs for those in Phase II and III clinical trials.
Strategy 5	Design and implement strategies to increase participation in clinical trials; increase the number and type of clinical trials available in Montana.

Objective II.2: *Increase the number of researchers, research dollars, and studies devoted to community-based, clinical, basic science, translational, epidemiologic, genetic, and other cancer-related research.*

Baseline: To be determined

Outcomes: By 2008, determine the baseline for research dollars, studies, and researchers in Montana

By 2011, increase funds, active researchers, and the number of studies on cancer-related topics by numbers or percentages to be determined

Data sources: To be established

Strategy 1	Determine the level of research dollars, number of studies, and the number of active researchers working on cancer-related topics in Montana.
Strategy 2	Conduct an assessment to define the supportive infrastructure for research.
Strategy 3	Design strategies to enhance the level of research funding, increase the number of researchers, and improve the infrastructure for cancer research in Montana.
Strategy 4	Encourage and facilitate Montana's researchers in their applications for cancer-related funding.
Strategy 5	Support increasing culturally competent research in communities and populations with a disparate burden of cancer.

The mission of translational research is to convert basic science into clinical applications, and to use clinical observations to generate scientific research. Translational research focuses on the integration of activities from bench to bedside.



Patricia Lieberg's life changed completely in less than a month. Looking back, she realizes there'd been signs that something wasn't quite right. She felt as if she'd pulled some muscles, but couldn't explain why. She'd developed some facial hair, experienced flushing and shortness of breath.

She finally went to see her doctor. He ordered an ultrasound, which revealed what appeared to be a large tumor on her kidney. He referred her to a specialist in Great Falls, who immediately ordered an MRI. The results revealed that the tumor wasn't on her kidney after all: the

adrenal tumor had grown up into the vena cava, the large vein that returns blood to the heart. Patricia had adrenocortical carcinoma, which affects about one in two million people. After looking at the MRI results, the doctor said, "I don't even want to touch you here. You need to be in Bethesda, Maryland. They're the specialists."

Once there, they removed the adrenal tumor; by then, the tumor had invaded her heart and lungs. The operation went well, and Patricia flew home two weeks later. They'd told her to come back in six months for a follow-up CAT scan. The more she thought about it, the more uncomfortable she became with the idea of waiting. She asked her physician to order a CAT scan locally. It's a good thing she did: it revealed that the cancer nodules were growing. Neither radiation nor surgery would help. Her best hope was a clinical trial.

Patricia agreed to participate in the trial that included new chemotherapy drugs. She has now been through seven treatments in Bethesda, with three or four weeks between treatments. Because she's participating in a clinical trial, they help with airfare and some of her other expenses. Last time they checked, her doctors were delighted to find that some of the smaller nodules had disappeared, and others had shrunk. It's great cause for celebration: this cancer is so invasive that the treatment is considered a success if the cancer doesn't continue to grow.

"The clinical trial was a great choice for me. Otherwise I'd be dead or close to it by now — the cancer was that bad and had gone that far. My family has been so supportive, but this has changed all of us a lot. You definitely realize what's important. If I could help others, I'd want to them to know how important it is to keep a positive attitude, and to refuse to give up. There will be down days and days you don't feel good, but you have to remember there will be good ones, too. Just don't give up." — Patricia Lieberg

New technology, if used wisely, can yield great benefits. If used indiscriminately, it can add unnecessary costs. Researchers must determine best-use scenarios before promoting wide use. Clinical trials help determine the most efficient, safe, appropriate, and effective use of new technologies.

Research: What You Can Do

- Become knowledgeable about cancer research in the state.
- Support public policy and legislation promoting:
 - increased cancer research.
 - funded cancer research in Montana.
- Become an ambassador for participation in cancer clinical trials and support the application of the information gained from these trials.
- Ask your doctor about clinical trials that you or a family member may agree to participate in.
- Support local fund raisers that provide funding for cancer research in Montana.

The Montana Cancer Consortium

is a nonprofit organization whose mission it is to bring state-of-the-art cancer treatment to Montana and Northern Wyoming through clinical trials sponsored by the National Cancer Institute (www.mtcancer.org).